

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter Richardson                      Art Unit : 1614  
Serial No. : 10/537,564                      Examiner : Unknown  
Filed : August 28, 2006                      Conf. No. : 4551  
Title : USE OF SPONGOSINE FOR THE TREATMENT OF PAIN

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR CORRECTED OFFICIAL FILING RECEIPT

Please correct the Filing Receipt for the above-referenced application to include the correct title of the application as amended in a Preliminary Amendment filed June 3, 2005 (copy enclosed). The correct title should read as follows:

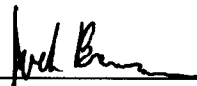
**USE OF SPONGOSINE FOR THE TREATMENT OF PAIN**

Please supply a corrected Filing Receipt to the undersigned with respect to this application. A copy of the original Filing Receipt showing the desired changes in ink is attached for your convenience.

No fee is believed to be due. If, however, there are any charges or credits, please apply them to Deposit Account No. 06-1050, referencing Attorney Docket No. 13425-170US1.

Respectfully submitted,

Date: November 17, 2006

  
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## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/537,564	08/28/2006	1614	1080	13425-170US1	5	21	1

CONFIRMATION NO. 4551

## FILING RECEIPT



\*OC000000020656929\*

26161  
 FISH & RICHARDSON PC  
 P.O. BOX 1022  
 MINNEAPOLIS, MN 55440-1022

Date Mailed: 10/03/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Peter Richardson, Cambridge, UNITED KINGDOM;

Power of Attorney: The patent practitioners associated with Customer Number **26161**.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/GB03/05379 12/09/2003

## Foreign Applications

UNITED KINGDOM 0228723.3 12/09/2002

If Required, Foreign Filing License Granted: 09/29/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/537,564**

Projected Publication Date: 01/11/2007

Non-Publication Request: No

Early Publication Request: No

## Title

Use of spongiosine-~~2-methoxyadenosine~~ for the treatment of pain, ~~in particular hyperalgesia~~

**Preliminary Class**

514

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

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Title 37, Code of Federal Regulations, 5.11 & 5.15**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter Richardson

Art Unit :

Serial No. :

Examiner :

Filed : Herewith

Title : USE OF SPONGOSINE FOR THE TREATMENT OF PAIN

Commissioner for Patents

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Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as indicated on the following pages.

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. ET322637910 US

June 3, 2005  
Date of Deposit

Applicant : Peter Richardson  
Serial No. :  
Filed : Herewith  
Page : 2 of 7

Attorney's Docket No.: 13425-170US1 / BV-1083 US

Amendments to the Specification:

Please replace the Title at page 1, line 1 with the following amended title:

USE OF SPONGOSINE (~~2-METHOXYADENOSEN~~) FOR THE TREATMENT OF  
PAIN, ~~IN PARTICULAR HYPERALGESIA~~

Please add the following new paragraph at page 1, line 3 after the Title:

Cross Reference to Related Applications

This application is a national phase filing under 35 U.S.C. § 371 of international application number PCT/GB2003/005379, filed December 9, 2003, which claims the benefit of priority of British application number 0228723.3, filed December 9, 2002. The disclosures of the prior applications are considered part of (and are incorporated by reference in) the disclosure of this application.

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-10. (Canceled)

11. (Original) A method of preventing, treating, or ameliorating pain which comprises administering spongostin to a subject in need of such prevention, treatment, or amelioration.

12. (Original) A method according to claim 11, wherein the pain is hyperalgesia.

13. (Original) A method according to claim 12, wherein the hyperalgesia is neuropathic pain.

14. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 13~~, wherein the pain is caused by or associated with a disease that causes damage to sensory neurons ~~neurones~~.

15. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 14~~ for the prevention, treatment, or amelioration of bowel pain, pancreatic pain, pelvic/perineal pain, back pain, lower back pain, chest pain, cardiac pain, pelvicpain/PID, joint pain (~~for example, associated with tendonitis, bursitis, acute arthritis~~), neck pain, obstetric pain (~~labour or Caesarean Section~~), cancer pain, HIV pain, phantom limb pain, post-operative pain, chronic neuropathic pain, failed back surgery pain, post physical trauma pain (~~including pain caused by a gunshot wound, a road traffic accident, or a burn~~), scar tissue pain, acute herpes Zoster pain,

acute pancreatitis breakthrough pain (~~cancer~~), post-herpes neuralgia, or trigeminal neuralgia, or for the prevention, treatment, or amelioration of neuropathic or other pain caused by, or associated with diabetic neuropathy, polyneuropathy, fibromyalgia, myofascial pain syndrome, osteoarthritis, rheumatoid arthritis, sciatica or lumbar radiculopathy, spinal stenosis, temporomandibular joint disorder, renal colic, or dysmenorrhoea/endometriosis.

16. (Original) A method according to claim 12, wherein the hyperalgesia is inflammatory pain.

17. (Currently Amended) A method according to claim 11, ~~12, or 16~~, wherein the pain is caused by or associated with an inflammatory or immune disease.

18. (Currently Amended) A method according to claim 11, ~~12, 16, or 17~~ for the prevention, treatment, or amelioration of bowel pain, back pain, cancer pain, fibromyalgia, post-operative pain, or for the prevention, treatment, or amelioration of inflammatory or other pain caused by, or associated with arthritic conditions, ~~such as osteoarthritis, rheumatoid arthritis, rheumatoid spondylitis, gouty arthritis, or~~ asthma, chronic obstructive pulmonary disease, fibrosis, multiple sclerosis, sepsis, septic shock, endotoxic shock, gram negative shock, toxic shock, hemorrhagic shock, adult respiratory distress syndrome, cerebral malaria, organ transplant rejection, pain secondary to cancer, HIV, chronic pulmonary inflammatory disease, silicosis, pulmonary sarcosis, bone resorption diseases, reperfusion injury, graft v. host rejection, multiple sclerosis, myasthenia gravis, allograft rejections, fever and myalgia due to infection, AIDS related complex (ARC), keloid formation, scar tissue formation, Crohn's disease, ulcerative colitis and pyresis, irritable bowel syndrome, osteoporosis, cerebral malaria, bacterial meningitis, or adverse effects from amphotericin B treatment, interleukin-2 treatment, OKT3 treatment, or GM-CSF treatment.



19. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18~~, wherein spongostin is administered at a dose that gives rise to plasma concentrations one fifth to one thousandth of the minimum plasma concentration of spongostin that gives rise to bradycardia, hypotension or tachycardia side effects in animals of the same species as the subject to which the dose is to be administered.

20. (Currently Amended) A method according to claim 19, wherein the dose is one fifth to one hundredth of the minimum dose ~~does~~ that gives rise to the side effects.

21. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18~~, wherein spongostin is administered at a dose that is one fifth to one fiftieth of the minimum dose of spongostin that gives rise to bradycardia, hypotension or tachycardia side effects in animals of the same species as the subject to which the dose is to be administered.

22. (Original) A method according to claim 21, wherein the dose is one fifth to one tenth of the minimum dose that gives rise to the side effects.

23. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18~~, wherein spongostin is administered at a dose of less than 6mg/kg.

24. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18, or 23~~, wherein spongostin is administered at a dose of at least 0.01mg/kg, ~~preferably at least~~ 0.05mg/kg.

25. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18, or 23~~, wherein spongostin is administered at a dose of at least 0.1mg/kg.

26. (Currently Amended) A method according to claim 25, wherein spongosome is administered at a dose of 0.1 to 1mg/kg, ~~or 0.2 to 1mg/kg.~~

27. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 18~~, wherein the subject is administered with spongosome and another analgesic agent.

28. (Original) A method according to claim 27, wherein the other analgesic agent is an opioid receptor agonist or partial agonist, a cyclooxygenase inhibitor, a sodium or calcium channel modulator, a Selective Serotonin Reuptake Inhibitor (SSRI), or an agent that treats neuropathic pain.

29. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 28~~, wherein spongosome is administered orally, parenterally, sublingually, transdermally, intrathecally, or transmucosally.

30. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 29~~, wherein spongosome is administered at a frequency of 2 or 3 times per day.

31. (Currently Amended) A method according to claim 11 ~~any of claims 11 to 30~~, wherein the subject is a human subject.

Applicant : Peter Richardson  
Serial No. :  
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Page : 7 of 7

Attorney's Docket No.: 13425-170US1 / BV-1083 US

REMARKS

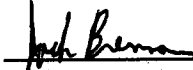
Claims 11-31 are pending in the application. Claims 1-10 have been canceled without prejudice. Claims 14, 15, 17-21, 23-27, and 29-31 have been amended to remove multiple dependencies and to remove or modify selected claim language. The specification has been amended to amend the title and insert the priority information on the first page of the application. These amendments add no new matter.

Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 13425-170US1.

Respectfully submitted,

Date: \_\_\_\_\_

June 3, 2005



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